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REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 1-22, 24, 25, 27-29, 33-38 and 40-67 are pending and are under examination in this application, and have been rejected in the Office Action dated August 28, 2007.

Applicants have herein amended claims 1, 2, 3, 16, 25, 29, 34, 47 and 66. It is submitted that these amendments add no new matter.

35 U.S.C. § 112 Rejections

In the Office Action, the Examiner rejected Claims 2, 3 and 29 under 35 U.S.C. §112, first paragraph, as not complying with the enablement requirement. According to the Examiner, claim 2 recites "preventing beta cell death", claim 3 recites "protection from diabetes" and claim 29 recites "prophylactically sparing beta cell function", and Applicants have not enabled the absolute prevention of all beta cell death and the outright prevention of diabetes, because it would require "undue experimentation" to practice the claimed invention of these claims.

In response, Applicants disagree that the claims as presently written recite absolutes, as interpreted by the Examiner, or that the application is required to enable absolutes. Applicants do not agree that claim 2 recites "preventing all beta cell death or dysfunction", that claim 3 recites "absolute protection from diabetes" or that claim 29 recites "prophylactically sparing all beta cell function", as one with ordinary skill in the art would understand and interpret these claims without the absolutes imparted therein by the Examiner. However, in order to expedite prosecution, Applicants have amended claim 2 to recite "substantially reducing the incidence of beta cell death or dysfunction", have amended claim 3 to recite "long term reduction in the

incidence of developing overt diabetes", and have amended claim 29 to recite "prophylactically reducing beta cell function". Applicants respectfully request that the Examiner withdraw these rejections.

In the Office Action, the Examiner also rejected Claims 1-22, 24, 27-298, 33, 35-38, 47, 48, 66 and 67 under 35 U.S.C. §112, first paragraph, as not complying with the written description requirement. According to the Examiner, these claims recite that the delivery agent "comprises" 4-CNAB, and the specification teaches that the delivery agent is 4-CNAB. In response, and in order to expedite prosecution, Applicants have amended claims 1, 16, 47, 66 to delete the word "comprises" such that these claims now recite "the delivery agent 4-CNAB". With regard to claims 48 and 67, which recite "said pharmaceutically acceptable delivery agent comprises about 300 mg 4-CNAB", Applicants contend that these claims refer to the amount of 4-NAB present in the composition. In any event, this language is identical to original claim 33, as mentioned by the Examiner. Applicants respectfully request that the Examiner withdraw this rejection.

35 U.S.C. § 103 Rejections

The Examiner previously asserted that "the instantly claimed invention is not described in any of the [priority] provisional applications," because "[t]he provisional applications make reference to "nighttime," but not "bedtime." In response, Applicants pointed out to the Examiner that both the specification and claims of each of U.S. Patent Applications 60/438,195, 60/438,451 and 60/478,967 do in fact refer to oral administration of insulin "at bedtime", and the instant application is entitled to claim priority from those provisional applications. The Examiner now contends, without providing any evidence in support of his contention, that "the inventions which are described by those claims in the provisional applications which recite the term 'bedtime' are different from those presently claimed."

Applicants again argue that the Examiner is incorrect and contend that each of the claims now rejected by the Examiner finds support in one, if not all, of the priority provisional applications. Regarding independent claim 34, Applicants refer the Examiner to U.S. Patent Application No. 60/438,451, filed January 6, 2003, at paragraphs [0041], [0048] and [0049]. In

addition, regarding independent claim 25, Applicants refer the Examiner to U.S. Patent Application No. 60/438,451, filed January 6, 2003, at paragraphs [00170]-[00179]. Regarding dependent claims 40-46 and 49, which depend from claim 25, and claims 50-65, which depend from claim 34, Applicants note that these claims find virtual *ipsis verbis* support either in the claims or specification of U.S. Patent Application No. 60/478,967, filed June 16, 2003, if not in U.S. Patent Application No. 60/438,451, filed January 6, 2003.

Should it be required by the Examiner, Applicants are prepared to point out the support for each and every one of the claims herein rejected by the Examiner. However, if support in the priority provisional applications remains an issue in this application, Applicants request that that the Examiner, under 37 C.F.R. § 1.104 and M.P.E.P. § 707 et seq., provide a complete listing of the claims that are alleged to lack support in the priority provisional applications.

In the Office Action, the Examiner rejected Claims 25, 34, 40-46, 49 and 50-65 under 35 U.S.C. § 103 as being unpatentable over:

(a) Pilarski (U.S. Patent No. 7,137,951) in view of Byrd (U.S. Patent No. 7,118,762) or Moye Sherman (U.S. Patent No. 7,115,663) or Ekwuribe (U.S. Patent No. 7,084,114) or Ekwuribe (U.S. Patent No. 7,060,675). According to the Examiner, Pilarski discloses administration of insulin at bedtime but does not specify oral administration, and each of Byrd, Moye-Sherman, Ekwuribe '114 and Ekwuribe '675 discloses oral administrable forms of insulin.

(b) Ekwuribe (U.S. Patent No. 7,060,675), which allegedly discloses oral administrable insulin.

(c) over Miller et al. (Clinical Pharmacology and Therapeutics 53(3), 380-4, 1993) in view of Mesiha et al. (International Journal of Pharmaceutics 249(1-2), 1-5, 2002), Hosny et al. (International Journal of Pharmaceutics 237(1-2), 71-6, 2002), or Clement et al. (Diabetes Technology & Therapeutics 4(4), 459-66, 2002. According to the Examiner, Miller et al. disclose that administering insulin at bedtime could be beneficial but does not disclose oral administration of insulin, and each of Mesiha et al., Hosny et al. and Clement et al. disclose orally administering insulin.

(d) over Yki-Jarvinen et al. (Annals of Internal Medicine 130(5), 389-96, 1999) in view of Mesiha et al., Hosny et al., or Clement et al. According to the Examiner, Yki-Jarvinen et al.

disclose that administering insulin at bedtime could be beneficial but does not disclose oral administration of insulin, and each of Mesiha, Hosny and Clement disclose orally administering insulin.

Applicants traverse these rejections. Applicants have herein amended independent claims 25 and 34 to recite that, in addition to the insulin, an effective amount of a pharmaceutically acceptable delivery agent 4-CNAB which facilitates absorption of said insulin from the gastrointestinal tract is also administered at or shortly before bedtime. In view of these amendments to claims 25 and 34 , Applicants believe that amended claims 25 and 34 are allowable, as none of the Pilarski, Byrd, Moye-Sherman, Ekwuribe '114, Ekwuribe '675, Miller et al., Mesiha et al., Hosny et al., Clement et al. or Yki-Jarvinen et al. references disclose orally administering insulin and a pharmaceutically acceptable delivery agent 4-CNAB which facilitates absorption of said insulin from the gastrointestinal tract at or shortly before bedtime. Accordingly, amended independent claims 25 and 34 are now allowable, and Applicants request that the Examiner withdraw these rejections.

Regarding dependent claims 40-46 and 49, which depend from amended independent claim 25, and claims 50-65, which depend from amended independent claim 34, these claims also overcome the rejections by virtue of their dependence on amended independent claims 25 and 34, and Applicants respectfully request that they be passed to allowance.

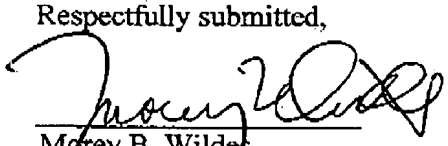
In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number

below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,



Morey B. Wildes
Attorney/Agent for Applicant(s)
Registration No. 36,968

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Pearl Cohen Zedek Latzer, LLP
1500 Broadway, 12th Floor
New York, New York 10036
Tel: (646) 878-0800
Fax: (646) 878-0801